510(k) Summary

MAY 12 2010

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

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510(k) Correspondent

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Date Prepared

April 30, 2010

Trade Name of Device

Navigator™

Common Name of Device

Computer, diagnostic, pre-programmed, single-function

Classification Name

Single function pre-programmed diagnostic computer

510(k) Classification

Class II 21 CFR 870.1435

Predicate Devices

The Navigator is substantially equivalent to the following predicate device(s):

- *K072735 Pulsion PiCCO$_2$*
- *K023960 LiDCOplus Hemodynamic Monitor*

Device Description

The Navigator is a physiologically integrated system designed to assist clinicians in the management of the systemic circulatory state in the critically ill patient.

Indications for Use:

The Navigator™ is indicated for the acquisition, processing, and display of hemodynamic parameters, in order to assist the clinician in achieving and maintaining a prescribed target hemodynamic stability.

Mean Systemic Filling Pressure (P_{ms}) and Heart Efficiency (E_h) parameters are calculated by the Navigator from Cardiac Output (CO), Mean Arterial Pressure (MAP) and Right Atrial Pressure (RAP) data, obtained directly from patient monitoring equipment, and other data obtained by manual clinician entry. The Navigator system provides a visual indication of the patient's circulatory status in relation to predetermined goals.

Intended Use

The Navigator ™ is valuable in any environment where resuscitation, stabilization and optimization of hemodynamic and oxygen metabolism is required. It provides clinicians with monitoring and support information that assists with management of the circulatory state of critically ill patients. The device provides clinicians with a graphical display of monitoring and support information as a visual aid in determining a patient's circulatory state. Navigator ™ is used in conjunction with standard monitoring in the following environments including:

- *Intensive care*
- *OR/anesthesia*
- *High dependency and step-down units*
- *Emergency departments*
- *Coronary care*
- *Acute care.*

This includes a broad range of patients (between the ages of 15-90 and weights of 40-150 kilograms) with unstable circulations presenting to the intensive care unit (ICU) or critical care units and those undergoing or suffering from:

- *Pre post open heart surgery.*
- *Pre post major surgery.*
- *Sedated patients.*
- *Drug overdose*
- *Septic shock.*
- *Renal failure*
- *Major burns.*
- *Major trauma.*
- *Hypovolemic shock*
- *Cardiogenic shock*

The device is applicable to critically ill patients requiring circulatory support in whom MAP, RAP and CO are being monitored regularly.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to standard ISO 14971:2007.

Non-C ical Testing

Non-cl al testing was performed in order to validate the design against the company's specific esign requirements, and to assure conformance with the following voluntary standar

IEC 60(01-1: Medical Electrical Equipment – Part 1: General Requirements for Safety (1988), includir mendment 1 (1991) & Amendment 2 (1995).

BS EN 01-1-2:2002, incorporating amendment A1:2006. This standard is identical with EMC s ard IEC 60601-1-2:2001, incorporating amendment 1:2004: Medical electrical equipm - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic Compa ity - Requirements and Tests (Edition 2:2001 with Amendment 1:2004).

Rigorou s oftware verification and validation testing was successfully performed by an indepen t software testing service. Testing included verification and validation to approved Naviga System Requirements, Operational Requirements, and Data Processing Requirements.

The co nation of Electrical Safety testing, EMC testing, and Software Verification and Valida provide a high level of confidence that both the Navigator hardware and software are at least afe and effective as the predicate devices.

Clinic Testing

Applie ysiology Pty Ltd conducted multi-center, open, randomized, controlled human clinica ls in order to collect safety and efficacy data supporting substantial equivalence.

Metho ogy:

Follow rgery, eligible patients were to be randomized on admission to ICU to receive care guided avigator™ or conventional care while CO was being monitored. All patients were to be con to the Navigator™. The screen of the patients in the control group was to have the graphic ction blank, the right hand side was to display actual values of MAP, CO and Right Atrial P re (RAP) as slaved from the bedside monitor, along with the patient's screening and randon ion number and initials. The arm of the study to which the patient was randomized (contr vigator™), was also to be shown.

Numb subjects (planned and analyzed):

Suffici ients were to be consented to allow 100 patients to complete the study (50 in each treatme m). A total of 112 patients were enrolled into the study and formed the intent to treat popula O. these, 107 patients completed the study as planned. A total of 105 patients formed the mo intent to treat (MITT) population (57 patients in the Navigator™ arm and 48 patient he control arm) these being the patients connected to Navigator™ with three hours or more o .

Effica sults:

The pr ndpoint was the average distance (mean standardized) to the central point of the target c scular zone over the period the patient was connected to the Navigator™.

The st nstrated non-inferiority to Navigator over conventional care. There was no statisti significant difference between the two treatment arms with regards to the mean standa l distance to the central point of the cardiovascular zone.

Safet lts:

All 11. ts enrolled in the study were included in the safety evaluation. Adverse events were c e. from the time that the patient was connected to Navigator™ until the follow up

visit. S us adverse events were collected from the time the patient was randomized until the follow isit.

Four h ed and thirteen (413) adverse events involving 99 patients (52 (88.1%) patients in the Navig arm and 47 (88.7%) patients on the conventional care arm) were reported during the study.

The mo equently reported adverse events were anaemia, hyperglycaemia, decreased haemo n, hypotension and abnormal blood glucose. None of the adverse events experienced by pa on the Navigator™ arm or the conventional care arm of the study were considered to have a io.ship to the device.

One p was withdrawn from the study due to an adverse event (cardiac tamponade consid o e serious but not related to the device). Two patients died during the study due to events idered to be not related to the device.

Ten (1 vi e incidents occurred during the study, but none were associated with any clinical comp ns. All occurrences were recognizable by the operator or physician, and necessary correct w re made in the production device. These incidents fell into the following categor

- *F* *occ* *currences of Navigator screen buttons or settings that did not function as intended. These c were recognizable by the operator.*
- *Fou* *dat* *currences of data communication problems with peripheral equipment or failure to display p ipheral equipment.*
- *On* *sta* *rrence where a Swan-Ganz catheter appeared to be incorrectly positioned on x-ray and confident of MAP, CO and CI readings.*
- *On* *wa* *rrence where a discrepancy was reported with MAP display when an aortic balloon pump te.*

Thirty) serious adverse events involving 24 patients (12 on the Navigator™ arm and 12 on the ional care arm) were reported during the study. No serious adverse events were consid e device related.

Reviev rse events per treatment group, suggested no trends in the presentation (type, frequer severity) of adverse events per study arm.

Conc

The st nstrated non-inferiority to Navigator over conventional care. There was no statist ificant difference between the two treatments arms with regards to the mean stand stance to the central point of the cardiovascular zone.

The in of adverse events and serious adverse events was comparable across the two study arms, w ends in the type, frequency or severity of event. No adverse or serious adverse events nsidered to be related to Navigator™.

Devic ts which occurred during the study were not associated with any clinical comp nd did not impact on patient safety.

Data at the use of Navigator™ is safe when compared to conventional ICU care.

Subs l Equivalence

Applie logy Pty Ltd believes that the Navigator is safe and effective when used as instruc nowledgeable and trained personnel. Navigator performs at least as safely and effect nventional care using predicate devices, and is therefore substantially equivalent to the rketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 12 2010

Applied Physiology Pty., Ltd.
c/o Mr. Robert N. Clark
President and Senior Consultant
Medical Device Regulatory Advisors, Inc.
4251 Kipling Street, Suite 565
Wheat Ridge, CO 80033-2899

Re: K092219
Device Name: Navigator™ Clinical Guidance System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single function pre-programmed diagnostic computer
Regulatory Class: Class II (Two)
Product Code: DXG
Dated: April 30, 2010
Received: May 7, 2010

Dear Mr. Clark

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092219

Device Name: Navigator™

Indications for Use:

The Navigator™ is indicated for the acquisition, processing, and display of hemodynamic parameters, in order to assist the clinician in achieving and maintaining a prescribed target hemodynamic stability.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092219